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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,738	09/26/2001	Naosuke Maruyama	5576-132	9282

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/23/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,738

Applicant(s)

MARUYAMA, NAOSUKE

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 3. 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low-substituted" in Claims 1, 2 and 10-16 is a relative term, which renders the claim indefinite. The term "low-substituted" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of this term cannot be determined which renders the claims indefinite. Claims 3-9 are also rejected since these claims do not correct this error.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu (WO 98/53798).

Applicant claims a base material for dry direct tableting, which is obtained by impregnating low-substituted hydroxypropyl cellulose with a sugar or a sugar alcohol and then drying it. Further limitations as seen in dependent claims include the degree of compaction, the flowability index, the identity of the sugar or sugar alcohol, and the amount of the sugar or sugar alcohol.

The Shimizu reference discloses a solid preparation that comprises a water-soluble sugar alcohol that may be selected as sorbitol and erythritol (see abstract), which are set forth in instant Claims 5-8, and a low-substituted hydroxypropyl cellulose (see abstract) as indicated in instant Claims 1, 2 and 9-16. See page 10, lines 23-25 of the Shimizu reference wherein the dosage forms of the solid preparation is preferably tablets, which embraces the "dry direct tableting" indicated in instant Claims 1-16. On page 9, lines 14-17, the Shimizu reference discloses that the water-soluble sugar alcohol is in an amount of 5 to 97 weight parts, per 100 weight parts of the solid preparation, which covers the amount of 30 to 100% by weight based on the low-substituted hydroxypropyl cellulose that is set forth in instant Claims 9-16. See page 15, lines 15-18 of the Shimizu reference wherein the strength of the solid preparation is usually about 2 to 20 kg, which embraces the degree of compaction of 35% or greater that is set forth in instant Claim 2. The instant claims differ from the Shimizu reference by claiming that the base material is for dry direct tableting.

The Koyanagi et al patent, which discloses hydroxypropyl cellulose having a hydroxypropyl radical-substituted moles per glucose unit from 0.1 to 1.30 (see column 2, lines 22, 29 and 30), shows that tableting hydroxypropyl cellulose by dry and direct compression is well known in the art. See column 3, last paragraph of the Koyanagi et al patent wherein Example 1 indicates that the mixtures, which include low substituted hydroxypropyl cellulose, were tableted by dry and direct compression method into tablets. The disclosure in the Koyanagi et al patent of the hydroxypropyl cellulose having a hydroxypropyl radical-substituted moles per glucose unit from 0.1 to 1.30

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embraces low-substituted hydroxypropyl cellulose. The present of lactose in the composition with the hydroxypropyl cellulose (see Table 1) embraces the use of a sugar with the hydroxypropyl cellulose that is set forth in instant Claim 1.

The instant claims also differ from the Shimizu reference and Koyanagi et al patent by claiming that the base material has a flowability index of 60 or greater. Shimizu and Koyanagi et al do not disclose the flowability index of their products. However, since virtually all of the other characteristics of the instant claims (such as the present of low substituted hydroxypropyl cellulose and a sugar or sugar alcohol, their concentration, degree of compaction, and their use for dry direct tableting) are set forth in the Shimizu reference and Koyanagi et al patent, the flowability index would be considered an inherent characteristic of the hydroxypropyl cellulose compositions of the Shimizu reference and Koyanagi et al patent. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

It is noted that the instant claims are set forth in the form of product-by-process claims, which are considered product claims by the Office. Applicants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

One of ordinary skill in this art would be motivated to combine the teachings of the Shimizu reference with the Koyanagi et al patent since both references disclose low-substituted hydroxypropyl cellulose compositions in the form of tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the low substituted hydroxypropyl cellulose composition of the Shimizu reference for dry direct tableting in view of the recognition in the art, as

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evidence by the Koyanagi et al patent, that low substituted hydroxypropyl cellulose composition is excellent as a shaping agent and as a binder for forming tablets.

Summary

5. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

6. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

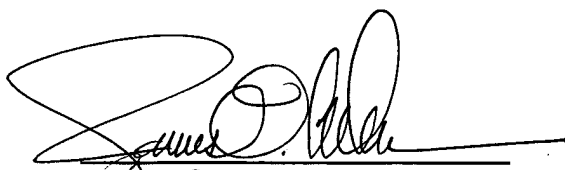
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600